Exhibit Q

TVT-Secur (Hammock) Versus TVT-Obturator: A Randomized Trial of Suburethral Sling Operative Procedures

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Objectives: This study aimed to compare TVT-Secur (TVT-S) and TVT-Obturator (TVT-O) suburethral slings for treatment of stress urinary incontinence (SUI).

Methods: This was a single-center, nonblinded, randomized trial of women with SUI who were randomized to TVT-S or TVT-O from May 2007 to April 2009. The primary outcome, SUI on cough stress test (CST), and quality-of-life and symptom questionnaires (Pelvic Floor Distress Inventory [PFDI-20] and Pelvic Floor Impact Questionnaire [PFIQ-7]) were assessed at 12 weeks and 1 year.

Results: Forty-three women were randomized to TVT-S and 44 to TVT-O. There were no differences in median baseline PFDI-20 and PFIQ-7. Twenty-two (52.4%) of 42 participants randomized to TVT-S had a positive CST result at evaluation after 12 weeks or 1 year, whereas 4 (9.1%) of the 44 in the TVT-O group had a positive CST result. The intent-to-treat analysis showed that the risk of a positive CST result was 6 times higher after TVT-S than TVT-O (risk ratio, 6.0; 95% confidence interval [CI], 2.3–16.0). Among women not lost to follow-up, the risk ratio for a positive CST result after TVT-S compared with TVT-O was 17.9 (95% CI, 2.5–128.0) at 12 weeks and 3.5 (95% CI, 1.1–11.0) at 1 year. Both TVT-S and TVT-O resulted in improved quality of life and symptoms at 12 weeks. There was no difference between the groups for PFDI-20 ($P = 0.40$) or PFIQ-7 ($P = 0.43$). A similar pattern was seen at 1 year ($P = 0.85$ and $P = 0.36$).

Conclusions: The TVT-S seems to have a higher risk of positive postoperative CST result; however, the procedures result in similar improvements in quality of life and symptoms.

Key Words: TVT-Secur, TVT-Obturator, stress incontinence, efficacy

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The International Continence Society defines stress urinary incontinence (SUI) as the complaint of involuntary leakage during effort or exertion or during sneezing or coughing.[1] Stress urinary incontinence affects 4% to 35% of women, and the prevalence increases with age.[2] Ten percent of middle-aged women report daily or severe incontinence and at least one-third report leakage at least weekly.[3]

Surgical techniques for the correction of stress incontinence have evolved during the past 100 years and have included Kelly plication, retropubic urethropexy (Marshall-Marchetti-Krantz, Burch), needle urethropexy, fascial and synthetic bladder neck, and, more recently, midurethral slings, which can be placed using either a retropubic or a transobturator approach.

Midurethral tension-free slings are minimally invasive procedures that have been shown to have high success rates and low overall complication rates.[4] Reported complications of retropubic slings such as Tension-Free Vaginal Tape (TVT; Ethicon Women's Health & Urology, Somerville, NJ) include those that are associated with the blind passage of the needle through the retropubic space, such as injury to the bladder, urethra, bowel, nerves, and vascular structures.[5] In an effort to reduce these complications, Delorme[6] introduced the transobturator approach, whereby the sling is passed using a lateral thigh approach through the obturator foramen. This technique was further modified with an inside-out approach as described by de Leval.[3] These techniques have been shown to have equivalent cure rates and seem to reduce the risk of serious complications. Several transobturator devices have been developed, such as Monarc (AMS, Minnetonka, MN) and Tension-Free Vaginal Tape Obturator (TVT-O; Ethicon). These devices have demonstrated short-term continence rates similar to the retropubic TVT technique, with failure rates (patient reported with confirmation by stress test and urodynamic studies) of 2.7% for TVT and 1.3% for TVT-O.[7] Complications seem to be fewer as well with the transobturator approach; Neuman[8] showed decreased rates of bladder perforation, intraoperative bleeding, and postoperative voiding difficulties.

In an attempt to further minimize postoperative complications and reduce the need for anesthesia, single-incision slings have been developed, such as TVT-Secur (TVT-S; Ethicon). Limited data are available with regard to this approach that mirrors the transobturator sling but requires less dissection, uses a smaller overall amount of mesh, and has no exit sites for the mesh. Early studies indicate a range of objective cure rates from 70.3% to 87.5%.[9,10]

The purpose of this randomized clinical trial was to compare objective outcomes, as well as changes in quality of life, after TVT-O and TVT-S ("Hammock" method) for the treatment of SUI.

METHODS

Approval for this study was obtained from the Mount Auburn Hospital Institutional Review Board. A nonblinded, randomized clinical trial was conducted, with all procedures being performed at Mount Auburn Hospital, Cambridge, Mass. Informed consent was obtained from each subject preoperatively.

On the basis of previously published data,[11] we hypothesized that one of the procedures would be successful for 80% of women while the other would be successful for 95% of women. Using a 1-sided test, the sample size required to have 80% power

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to detect this effect size with $\alpha = 0.05$ was 67 women in each treatment arm. The sample size was increased by 6 in each group to account for loss to follow-up.

Women were randomized in a 1:1 allocation to TVT-S or TVT-O. Each surgery assignment was kept in a sequentially numbered, opaque, and sealed envelope before the day of surgery. The surgeon was not aware of the assigned procedure until the morning of surgery when the envelope was opened. Patients were not blinded to the procedure postoperatively as they were made aware of differences in the procedure preoperatively; specifically, the presence of skin incisions in the medial thigh with the TVT-O and absence of them with the TVT-S. Only TVT-S and TVT-O devices were used.

Inclusion criteria were a history of SUI with a demonstrable impact of SUI as seen on quality-of-life questionnaires and a positive cough stress test (CST) result during urodynamic testing. Women were excluded if they had intrinsic sphincter deficiency (defined by a maximum urethral closure pressure [MUCP] of <20 cm H_2O), previous suburethral sling, or predominant overactive bladder symptoms. In addition, women planning a pregnancy, those who had an elevated postvoid residual (PVR >100 mL), those with bleeding condition or undergoing anticoagulant therapy, and those with immunosuppression, progressive neurological disease, or evidence of systemic infection were excluded.

Before surgery, women completed 2 quality-of-life and symptom questionnaires, namely, Pelvic Floor Distress Inventory (PFDI-20) and Pelvic Floor Impact Questionnaire (PFIQ-7), which include assessment of urinary, prolapse, and bowel symptoms. These questionnaires were chosen because patients in the study were permitted to undergo concomitant procedures to treat prolapse and/or fecal incontinence. The patients completed a voiding diary and underwent an evaluation that included a Q-tip test to determine the presence or absence of urethral hypermobility (>30 degrees from horizontal with straining), complex urodynamic testing (uroflowmetry, measurement of PVR, subtracted water cystometry, CST, and urethral pressure profilometry with measurement of MUCP). Women were also evaluated for the presence of prolapse, using the Pelvic Organ Prolapse Quantification measurement system. Those who had documented prolapse were not excluded from the study, but urodynamic testing was performed with prolapse reduction using scopettes. Subjects with urodynamic stress incontinence and symptomatic prolapse underwent a suburethral sling procedure with concomitant prolapse repair procedures as determined by the surgeon. Subjects who underwent a sling procedure alone had a weight lifting restriction of 5 lb for 2 weeks after surgery, and those who underwent concomitant procedures for prolapse had a 10-week restriction period.

Primary and secondary end points were assessed at approximately 12 weeks and 1 year after surgery. The primary end point was objective failure, as defined by the date of visit at which the presence of SUI was noted on a CST. The CST was performed before and after surgery with either 300 mL of instilled sterile saline or at maximum capacity if it was less than 300 mL. Secondary end points included PFDI-20, PFIQ-7, postoperative pain, PVR, mesh erosion or exposure, intraoperative estimated blood loss (EBL), length of procedure (time in minutes), and postoperative pain scale (verbal analog scale). Women were asked to rate their pain from 0 to 10, with 0 being no pain and 10 being the worst imaginable pain. They were asked to verbally rate their pain on postoperative days 1 and 7. Additional secondary outcomes included need for sling revision, length of postoperative catheterization, and need for a second anti-incontinence procedure.

An interim analysis was not initially planned as part of the study; however, several investigators voiced concerns about noting an increasing number of positive postoperative CSTs in women who has undergone a TVT-S. This analysis was performed on August 2009, and results are presented here. We performed an intent-to-treat analysis for the primary outcome assuming that all patients with a missing primary outcome had a negative postoperative CST result. We also conducted a separate analysis and conservatively assumed that all patients with a missing primary outcome had a positive postoperative CST result. In addition, we evaluated the risk of a positive CST result at 12 weeks and 1 year with a per-protocol analysis, including only those patients who presented for a CST at each time point. Data are presented as mean (SD), median (interquartile range), and proportions; comparisons were made using t test, Mann-Whitney U test, or χ^2 test. Risk ratios (RR) and 95% confidence intervals (CIs) were calculated using log-binomial regression.

RESULTS

The study was terminated early because of the interim analysis results. Forty-three women were randomized to TVT-S and 44 to TVT-O. One woman in the TVT-S group was excluded before the procedure was performed because it was determined that she did not meet the inclusion criteria, leaving a total of 42 women in the TVT-S group.

Age, parity, menstrual status, presence of preoperative urgency, body mass index, Pelvic Organ Prolapse Quantification stage, and MUCP were not significantly different between groups (Table 1). There were no differences in median baseline PFDI-20 and PFIQ-7 (Table 1).

TABLE 1. Patients' Characteristics Before Surgical Procedure

Characteristic	TVT-S	TVT-O	*P*
Randomized, n	42	44	
Age, y	52.0 (45.0–62.0)	50.5 (45.5–60.0)	0.89
Body mass index, kg/m^2	29.7 (25.2–32.4)	29.3 (24.9–33.7)	0.72
Parity			0.20
0	5 (11.9)	2 (4.6)	
1	10 (23.8)	6 (13.6)	
≥2	27 (64.3)	36 (81.8)	
Menstrual status			0.41
Premenopausal	18 (42.9)	20 (45.5)	
Perimenopausal	4 (9.5)	8 (18.2)	
Postmenopausal	20 (47.6)	16 (36.4)	
Preoperative urge			0.16
Present	30 (71.4)	25 (56.8)	
Absent	12 (28.6)	19 (43.2)	
Preoperative stage			0.61
0	3 (7.1)	4 (9.1)	
1	21 (50.0)	17 (38.6)	
2	9 (21.4)	16 (36.4)	
3	6 (14.3)	5 (11.4)	
4	1 (2.4)	0 (0.0)	
Unknown	2 (4.8)	2 (4.6)	
Preoperative MUCP, cm H_2O	59.0 (46.0–71.0)	52.5 (45.0–59.5)	0.21
Preoperative PFDI-20	92.7 (47.9–124.0)	60.3 (50.0–89.6)	0.16
Preoperative PFIQ-7	38.1 (14.3–66.7)	33.3 (14.3–47.6)	0.23

Data are presented as median (interquartile range) or n (%), as appropriate.

The proportion of patients with concomitant surgery and EBL did not differ. More time was required to perform the TVT-O than the TVT-S procedure ($P < 0.0001$; Table 2).

There was no difference in median self-reported pain on postoperative day 1 ($P = 0.20$); however, the TVT-O group reported more pain on day 7 ($P = 0.046$; Table 3). Days of catheterization ($P = 0.46$) and need for sling revision ($P = 0.49$) were similar in both groups. By 1 year, mesh exposure was noted in 8 (19.1%) women who had TVT-S and 0 (0.0%) woman who had TVT-O ($P = 0.002$). After TVT-S, 8 women (19.1%) had a second operation by 1 year to correct persistent or recurrent SUI (as confirmed by complex urodynamic testing with a positive CST result) compared to 0.0% after TVT-O ($P = 0.002$).

Three women (7.1%) in the TVT-S group and 3 women (6.8%) in the TVT-O group were lost to follow-up and did not present for either the 12-week or 1-year evaluation. One additional woman (2.3%) randomized to TVT-S and 2 women (4.5%) randomized to TVT-O provided some follow-up data, such as PFDI and PFIQ questionnaires, but did not have a CST at any time. These participants were included in the intent-to-treat analysis. There was no difference ($P = 0.71$) in the mean length of follow-up in the TVT-S group (8.2 [5.3] months) compared with the TVT-O group (8.6 [5.2] months).

Although 23 (54.8%) of the 42 participants randomized to TVT-S had a positive CST result at either postoperative evaluation, only 4 (9.1%) of the 44 participants in the TVT-O group had a positive CST result at 12 weeks or 1 year after surgery (Table 4). The intent-to-treat analysis showed that the risk of a positive postoperative CST result was 6 times higher after TVT-S than after TVT-O (RR, 5.8; 95% CI, 2.2–15.3). When assuming all missing CST results were positive, there was a 3-fold increase in risk of a positive postoperative CST result with TVT-S compared with TVT-O (RR, 3.1; 95% CI, 1.7–5.9). In addition, the time to a positive CST result was shorter ($P = 0.0002$) with TVT-S (8.2 [5.0] months) than with TVT-O (13.1 [0.8] months).

The RR for a positive CST result among women who were evaluated at 12 weeks was 17.9 (95% CI, 2.5–128.0) for TVT-S compared with TVT-O. Among those who returned at 1 year, the RR was 3.5 for TVT-S compared with TVT-O (95% CI, 1.1–11.0). The corresponding proportions for the per-protocol analysis are shown in Table 4.

Both TVT-S and TVT-O resulted in improved quality of life and symptoms from baseline to 12 weeks. There was no difference between the groups for either the PFDI-20 ($P = 0.40$) or the PFIQ-7 ($P = 0.43$). A similar pattern of improvement was seen at 1 year ($P = 0.85$ and $P = 0.36$; Table 5).

CONCLUSIONS

The results of this randomized trial indicate that TVT-S has a higher risk of positive CST result by 1 year after surgery; however, the TVT-S and TVT-O procedures result in similar improvements in quality of life and symptoms. In addition, the incidence of mesh exposure and subsequent operation to treat SUI were higher after TVT-S than after TVT-O.

When assessed at 1 year after surgery, the incidence of a positive CST result was 54.8% in the TVT-S group compared to 9.1% in the TVT-O group. The subjective cure rates, based on the quality-of-life and symptom questionnaires, however, indicate an overall improvement in quality of life and symptoms after both procedures.

Because of the significant difference noted in the primary outcome (CST) between groups at the time of this interim analysis, the study was terminated early. Given that the incidence of failure in the TVT-S group seemed significantly higher than that in the TVT-O group, we felt that patient care would be compromised by continuing the study.

The lower overall success of TVT-S could be attributed to the difficulty that was sometimes encountered in the detachment of the introducer from the sling. During the introducer removal process, the original tensioning may have been compromised, as the introducer was moved back and forth in an attempt to release the sling from the introducer. In the case of the TVT-O, we used

TABLE 2. Intraoperative Data

Characteristic	TVT-S (n = 42)	TVT-O (n = 44)	*P*
Concomitant surgery	20 (47.6)	22 (50.0)	0.83
EBL, mL	20.0 (20.0–30.0)	20.0 (10.0–30.0)	0.06
Sling procedure time, min	10.0 (8.0–12.0)	13.0 (12.0–17.0)	<0.0001

Data are presented as median (interquartile range) or n (%), as appropriate.

TABLE 3. Postoperative Clinical Outcomes

Characteristic	TVT-S (n = 42)	TVT-O (n = 44)	*P*
Pain on postoperative day 1	3.0 (1.0–3.5)	3.0 (1.0–5.0)	0.20
Pain on postoperative day 7	0.0 (0.0–1.0)	1.0 (0.0–3.0)	0.046
Length of catheterization, d	0 (0.0–1.0)	0 (0.0–1.0)	0.46
Mesh exposure			0.002
Yes	8 (19.1)	0 (0.0)	
Subsequent operation			0.002
Yes	8 (19.1)	0 (0.0)	
Sling revision			0.49
Yes	1 (2.4)	0 (0.0)	

Data are presented as median (interquartile range) or n (%), as appropriate.

TABLE 4. Primary Outcome

Characteristic	TVT-S	TVT-O	*P*
Intent-to-treat analysis			
Postoperative CST			
No. participants	42	44	
Positive	23 (54.8)	4 (9.1)	<0.0001
RR (95% CI)	6.0 (2.3–16.0)	Ref	
Per-protocol analysis			
CST at 12 wk			
No. participants evaluated	36	38	
Positive	17 (47.2)	1 (2.6)	<0.0001
Negative	19 (52.8)	37 (97.4)	
RR (95% CI)	17.9 (2.5–128.0)	Ref	
CST at 1 y			
No. participants evaluated	20	23	
Positive	9 (45.0)	3 (13.0)	0.04
Negative	11 (55.0)	20 (87.0)	
RR (95% CI)	3.5 (1.1–11.0)	Ref	

Data are presented as n (%).

TABLE 5. Quality-of-Life and Symptom Questionnaires

Characteristic	n	TVT-S	n	TVT-O	*P*
Reduction in PFDI-20 at 12 wk	35	47.9 (20.8–82.3)	39	39.6 (21.9–66.7)	0.40
Reduction in PFIQ-7 at 12 wk	34	28.7 (9.5–47.6)	39	23.8 (9.5–42.8)	0.43
Reduction in PFDI-20 at 1 y	16	37.0 (21.5–73.4)	20	48.4 (28.7–60.4)	0.94
Reduction in PFIQ-7 at 1 y	17	33.3 (7.6–42.9)	20	23.8 (14.3–42.8)	0.48

Data are presented as median (interquartile range).

the method of tensioning with a Babcock clamp as originally described by de Leval.[3] Using this technique, the mesh is consistently noted to be flat against the underlying suburethral tissue without tension.

Another point to consider is that the ends of the TVT-S are intended to be embedded within the obturator internus muscle, as opposed to passing through the obturator membrane as with the TVT-O sling. The TVT-S may theoretically migrate with time, detaching from the obturator internus muscle, whereas with TVT-O, the mesh passes through the obturator membrane as well as the obturator internus and externus muscles and the adductor magnus muscle and therefore may not be dislodged as easily. In other words, the latter approach may create a more reliable anchor for the mesh. In addition, excessive hydrodissection or sharp dissection of the periurethral space may affect the degree of attachment of the absorbable "fleece" on either end of the TVT-S. In addition, the attachment of the fleece could be compromised if a hematoma developed within the obturator internus muscle as a result of the surgical procedure.

There also was an increased incidence of mesh exposure in the TVT-S group. Although the etiology of this complication is unclear, we theorize that the sharper edges of the TVT-S introducer potentially create more trauma to the vaginal epithelium and may result in higher erosion rates.

There was lower incidence of postoperative pain at 1 week in the TVT-S group compared to that in the TVT-O group. This could be attributed to less dissection and trauma to the surrounding tissue in the placement of TVT-S compared to TVT-O, which does penetrate the obturator membrane. In addition, the TVT-S mesh does not pass through the adductor muscles of the thigh, which may be responsible for thigh pain.

Strengths of this study include the randomized design, the similar length of follow-up in the 2 groups, and the similar loss to follow-up. Limitations of this study include the early conclusion of the study without enrollment meeting adequate power. Another limitation to the study is the possibility that the learning curve for the procedure is greater, particularly with the removal of the introducer of the TVT-S, creating initial higher failure rates. Patients' self-reported outcomes may have been biased, however, based on expectations discussed preoperatively, particularly with the description of pain.

The patients, the surgeons, and the medical assistant who performed the postoperative testing were not blinded to the type of surgical procedure. However, the CST was performed according to a standard protocol and is an objective test; therefore, it is unlikely that the lack of blinding resulted in any bias of the primary outcome.

Despite the fact that the TVT-S group had higher postoperative CST, both groups had similar improvements in quality of life. Although the questionnaires did include urinary symptoms, they also evaluated prolapse and bowel dysfunction symptoms. This lack of difference may reflect the fact that the questionnaires were not specific to urinary symptoms alone or that patients were satisfied with an improvement in their symptoms despite a positive CST result.

Minimally invasive midurethral slings have become the primary choice of many surgeons in the treatment of SUI given their high long-term success rates when compared with traditional pubovaginal slings and Burch colposuspension. With the success of minimally invasive procedures, surgical device companies continue to develop and market less invasive products for the treatment of SUI. These devices, however, may be associated with potentially higher rates of complications, such as mesh exposure, and may not be equivalent in efficacy. To date, several case series have been published regarding surgeon experience with TVT-S with mixed outcomes. Lim et al[12] showed objective and subjective success rates at 6 months to be 58.3% and 51.3%, respectively; however, quality-of-life scores showed improvement. Cornu et al[13] showed a short-term success rate of 93.5%, but by the time of last follow-up, only 40% of women were cured. However, others like Khandwala et al[14] showed 83% success rates at a mean follow-up of 14 months. Few comparative trials have been performed between TVT-S and retropubic or transobturator slings. Those available for review report similar cure rates for TVT-S and the transobturator method at 83.8% versus 81.6%, respectively, when TVT-O was used and 71.0% and 84.8%, respectively, when Monarc was compared.[15,16]

Another type of single-incision sling currently available on the market, the MiniArc (American Medical Systems, Minnetonka, Minn) has some differences in design, with self-fixating tips that provide immediate fixation into the obturator muscles, with the process of disengagement of the needle from the tip different compared to the TVT-S, and which offers an optional redocking of the tip in the event that the sling needs to be tensioned tighter. A study by Kennelly et al[17] showed that at 1 year after the procedure, 90.6% of women had a negative CST result and quality-of-life questionnaires scores showed a statistically significant decrease. Pickens et al[18] showed that, at 12 months after surgery, their patients had a "cured/dry" rate of approximately 94% based on their response to question 3 on the Urogenital Distress Inventory regarding urine leakage related to physical activity, coughing, or sneezing and denial of stress-related leakage on direct questioning.

In this study, cure rates for TVT-S were lower compared with the TVT-O group. There was an increase in the incidence of erosion in the TVT-S group, as well as a higher incidence of subsequent operation because of either persistence of symptoms or recurrence. Despite these findings, however, the quality-of-life questionnaires showed improvement.

Given the inconsistent data of the published case series and the low long-term cure rates found in this present study, we believe that more level 1 evidence from properly designed randomized controlled trials is needed, as new surgical devices to treat stress incontinence are introduced to evaluate safety and efficacy.

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